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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Jersey District Office
Central Region
Waterview Corporate Center
10 Waterview Blvd. 3rd Floor
Parsippany, NJ 07054
Telephone: (973) 526-6000
FAX: (973) 526-6069

January 28, 1999

WARNING LETTER

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

Mr. Gerald Schreiber
President & CEO
J & J Snackfoods, Corporation
6000 Central Highway
Pennsauken, New Jersey 08109

File No.: 99-NWJ-13

Dear Mr. Schreiber:

On November 13-17, 1998, an Investigator from this office conducted an inspection of your pretzel manufacturing facility located at 6000 Central Highway, Pennsauken, NJ. A Form FDA 483, List of Inspectional Observations was presented at the conclusion of this inspection, citing serious deviations from Title 21 of the Code of Federal Regulations (CFR), Part 110 Current Good Manufacturing Practice (cGMPs), in Manufacturing, Packing or Holding Human Food, with respect to your product "Softstix Cheese Filled Soft Pretzel Sticks" being commingled with "Softstix Peanut Butter and Jelly flavored Soft Pretzel Sticks", causing it to be adulterated with the meaning of Section 402 (a)(1) of the Federal Food, Drug and Cosmetic Act (the Act), in that:

1. Your firm lacked adequate controls in place to protect products in the repackaging stage from being contaminated with products containing potential allergens. The warehouse computer control system was overridden allowing for three cases of "Softstix Peanut Butter and Jelly Filled Soft Pretzels" to be commingled with "Softstix Cheddar filled Soft Pretzels", which were repacked and distributed as "Schwan's Soft Stuffed Pretzels with Cheddar Cheese Filling", Lots 2448B and 2458C.

2. Your firm failed to provide adequate training for repacking operations in order to prevent the commingling of products with known allergens.

This inspection revealed that your firm conducted a voluntary recall after receiving complaints from customers. We note that this is the second recall conducted by your firm in two years that involved peanut filled pretzels commingled with cheese filled pretzels. The controls put in place during the previous recall, to prevent product mix-up during production, were not extended to the repacking operations.

The above list is not intended to be all-inclusive of deficiencies concerning your manufacturing practices. It is your responsibility to assure that products manufactured by your firm are in compliance with all requirements of cGMPs for food products. You should take prompt action to correct these deviations and institute effective measures to prevent reoccurrence at all levels of your operation. Failure to promptly correct these deviations may result in regulatory action being initiated by the agency without further notice. These actions may include seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps your firm has taken to correct the noted violations, including supporting documentation of procedures and training records. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the New Jersey District Office, FDA, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes Mota, Compliance Officer.

Sincerely,

Ray Wrahams for

Douglas I. Ellsworth
District Director
New Jersey District

RELEASE

REVIEWED BY _____ 2/3/99
C.O. DATE